

**REMARKS**

Applicant has considered the non-final office action mailed November 7, 2008 in connection with the above-identified patent application.

**Amendments to the claims**

Applicant amends claims 1 and 48 to attend to various clerical issues, and no new matter is entered thereby. Entry of the instant amendments into the file history of the above-identified application is respectfully requested.

**Applicant's Statement of Substance of Interview held October 8, 2008**

Applicant's representative, the undersigned, thanks Supervisory Examiner Mark L. Shibuya for courtesies extended on the occasion of a telephonic interview on October 8, 2008 with the undersigned, to discuss the status of the application. In particular, agreement was reached that the instant application should have not been abandoned and that the Notice of Abandonment dated October 6, 2008 was issued by mistake. Applicant now provides a statement of substance of the interview, as required by MPEP § 713.04.

Applicant's representative had discussed the office action mailed April 1<sup>st</sup>, 2008 with, variously, Examiner Cooke, Supervisory Examiner Le, and Special Program Examiner Burke, on April 28, 2008, with a view to requesting that the new requirement for restriction/election be vacated. On April 30, 2008, the undersigned had spoken with Supervisory Examiner Helms and received a confirmation that the requirement for restriction/election would be withdrawn and a new office action issued.

Applicant's representative placed several follow-up calls to Examiner Cooke to request an expected date by which a new office action would be issued (for example, on August 20, 2008, and September 30, 2008) prior to expiry of the due-date for response to the April 1<sup>st</sup>, 2008 action. On each occasion, Examiner Cooke assured the undersigned that a new office action was in preparation. In particular, on September 30, 2008, Examiner Cooke assured the undersigned that the application would "not be abandoned" and that a new office action would issue shortly.

In various follow-up calls between the undersigned and Examiner Cooke, and between the undersigned and Supervisory Examiner Shubiya in the first two weeks of October 2008,

including the call on October 8, 2008 at which the foregoing details were discussed, the undersigned was assured that a new office action would be issued.

Now that the office action dated November 7, 2008 has been issued, Applicant's representative thanks the Examiner and Supervisory examiners for their attention to this application, and ensuring that both the April 1<sup>st</sup> 2008 office action and the October 6, 2008 Notice of Abandonment were withdrawn.

### **REJECTIONS OF THE CLAIMS**

#### **Rejections under 35 U.S.C. § 103**

The Examiner has rejected various claims as allegedly obvious over two or more references in combination.

##### *Applicable legal standard*

For conciseness, Applicant prefacing the following remarks with a statement of the prevailing legal standard, applicable to all rejections.

The framework under which obviousness of a patent claim is judged was set forth by the U.S. Supreme Court in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966), and is as follows. Under § 103:

- the scope and content of the prior art are to be determined;
- differences between the prior art and the claims at issue are to be ascertained; and
- the level of ordinary skill in the pertinent art resolved.

Based upon the answers to these factual enquiries, the obviousness or nonobviousness of the claimed subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might also be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

Accordingly, and at a minimum, in order to establish obviousness of a claim, the prior art reference, or references when combined, must teach or suggest each and every limitation of the claimed invention. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Furthermore, and in instances where each and every limitation of the claimed invention can be found in a combination of references, an analysis of an apparent reason to combine the known elements in

the fashion claimed should be made explicit. *KSR Int'l. Co. v. Teleflex Inc.*, (550 U.S. \_\_\_, 127 S. Ct. 1727 (2007)).

Additionally, dependent claims are nonobvious under 35 U.S.C. § 103 “if the independent claims from which they depend are nonobvious.” *In re Fine* 837 F.2d 1071; 5 USPQ.2d 1596; MPEP 2143.03.

#### *Applicant's claims*

The pending claims are based on the measurements of affinities of groups of two or more lectins for various components of saliva from a subject, and correlating the pattern of binding with caries risk in the subject. In particular, the independent claims are as follows.

Claim 1 recites a method for predicting the risk of dental caries in a subject, based on binding of two or more lectins to binding components in the subject's saliva.

Claim 48 recites a method for preventing, or reducing the risk of, dental caries in a subject, based on binding of two or more lectins to binding components in the subject's saliva and administering to the subject a therapeutic agent.

Claim 49 recites a kit for detecting dental caries comprising means for measuring amounts of two or more lectin-binding components in a saliva sample.

Claim 60 recites an assay device for detecting the presence of two or more lectin-binding components in a saliva sample, comprising a matrix material having two or more lectins bound thereto.

#### *Examiner's rejection and cited references*

The Examiner has rejected Claims 1 – 4, 9, 16, 26, and 29 under 35 U.S.C. § 103(a) as allegedly being obvious over Seemann, *et al.*, *Caries Research*, Vol. 35, 156-161, (2001) (“Seeman”) in view of Akintoye, *et al.*, *Archives of Oral Biology*, Vol. 47, 337-345, (2002) (“Akintoye”).

The Examiner states that Seemann discloses a method of evaluating high and low caries susceptibility in children. Although Seeman differs from the instant claims in not specifically describing the measurement of two or more lectins, the Examiner points out that Akintoye discloses methods that use several lectins to characterize salivary adhesion-promoting protein

(APP). For instance, in Akintoye, seven lectins are utilized to determine the partial glycosylation patterns of saliva samples, and only two lectins (Jacalin and LEL) are found to be immuno-reactive for APP in three subjects, possibly due to individual variability.

*Applicant's response to Examiner's rejection*

As further discussed hereinbelow, the remaining claims are rejected over Seemann and Akintoye, in combination with one or more other references. Accordingly, Applicant begins with remarks that address the combination of Seemann and Akintoye alone in order to emphasize core aspects of the arguments that are also applicable to all of the rejections.

As acknowledged by the Examiner, Seemann does not disclose testing for caries in a subject by using multiple (*i.e.*, two or more) lectins, but instead discloses tests based on just one lectin (in particular, PNA). Furthermore, and as previously noted by Applicant in the response filed January 14, 2008 in the instant application, Seemann clearly shows that other lectins, either alone or in combination, were not likely to be suitable in diagnostic methods.

Akintoye discloses the partial characterization of salivary adhesion-promoting protein (APP). This is accomplished, according to Akintoye, by establishing binding of various lectins to terminal carbohydrates of APP. (*e.g.*, Akintoye at page 342, section 3.4; and page 344, left column, third paragraph). Although the Examiner states that Akintoye “taught the various lectins bind differentially in individual samples” and that “one of ordinary skill in the art would utilize multiple lectins in assay procedures in order to maximize the possibility of finding immunoreactivity” (Office Action at page 5), Applicant points out that lectins are only used by Akintoye in lectin blotting to identify the terminal carbohydrates of APP, not to evaluate caries risk. Furthermore, in Akintoye, to the extent that caries is referenced at all, it is not addressed by assaying lectins, but by Western blotting of APP with anti-APP antibodies (Akintoye at page 340, section 2.12). This procedure, according to Akintoye, actually showed no correlation between the immunoreactive pattern of APP and caries (Akintoye at page 342, section 3.5; and page 344, left column, fourth paragraph). Thus, there is nothing in Akintoye to imply or teach that multiple lectins should be used in assessing a subject’s risk to caries.

By contrast, lectins are used in the instant application and claims, not to characterize terminal carbohydrates of a protein, but to directly evaluate caries risk.

Thus, Claims 1 – 4, 9, 16, 26, and 29 are not obvious over the two cited references, and Applicant respectfully requests that the rejection be removed.

*The rejection over Seeman, Akintoye, and Foster*

The Examiner has rejected Claims 49 and 54-55, reciting kits, under 35 U.S.C. § 103(a) as allegedly being obvious over Seemann in view of Akintoye and further in view of Foster *et al.*, U.S. Pat. No. 4,444,879 (“Foster”), for reasons stated above, and because Foster discloses assay reagents in a kit form.

As addressed hereinabove, Seemann and Akintoye do not disclose the use of two or more lectins for assessing a subject’s susceptibility to caries. Foster does not disclose the teachings that are missing from Seemann and Akintoye; instead, Foster only discloses kits generally for assay reagents.

Thus, Claims 49, 54, and 55 are not obvious over the three cited references in combination, and Applicant respectfully requests that the rejection be withdrawn.

*The rejection over Seeman, Akintoye, and Shibuya*

The Examiner has rejected Claims 15, reciting a method, and 57-60, and 69, reciting an assay device, under 35 U.S.C. § 103(a) as allegedly being obvious over Seemann in view of Akintoye and further in view of Shibuya *et al.*, U.S. Pat. No. 4,582,795 (“Shibuya”).

Seemann and Akintoye do not disclose the use of two or more lectins for assessing a subject’s susceptibility to caries. Shibuya does not disclose use of lectins, either; instead, it only discloses a device that utilizes a very small amount of saliva (drop) for the diagnosis of dental caries.

Thus, Claims 15, 57-60, and 69 are not obvious over the three cited references, and Applicant respectfully requests that the rejection be withdrawn.

*The rejection over Seeman, Akintoye, and Sharon*

The Examiner has rejected Claims 6-8, 48, 75, and 76, reciting methods, under 35 U.S.C. § 103(a) as allegedly being obvious over Seemann in view of Akintoye and further in view of Sharon, *Adv. Exp. Med. Biol.*, Vol. 408, 1 – 8, (1996) (“Sharon”).

To reiterate, Seemann and Akintoye do not disclose the use of two or more lectins for assessing a subject's susceptibility to caries. Sharon does not disclose the use of lectins in this manner either; instead, it only discloses that carbohydrate lectin binding interactions are known and linked to various diseases.

Thus, Claims 6-8, 48, 75, and 76 are not obvious over the three cited references, and Applicant respectfully requests that the rejection be withdrawn.

*The rejection over Seeman, Akintoye, and Hume*

The Examiner has rejected Claims 61-68, reciting methods, under 35 U.S.C. § 103(a) as allegedly being obvious over Seemann in view of Akintoye and further in view of Hume, *J. Dental. Ed.*, Vol. 57, 439-443, (1993) ("Hume").

Seemann and Akintoye do not disclose the use of two or more lectins for assessing a subject's susceptibility to caries. Hume does not disclose such a use, either; instead, it only discloses that caries can be evaluated with multiple factors to determine whether the disease process begins, progresses, stops, or reverses. Applicant also notes that the Examiner has not specifically articulated where, in Hume, the teachings or disclosure are to be found that correlate with limitations recited in the individual claims 61 – 68.

Nevertheless, for at least the aforestated reasons, Applicant believes that Claims 61-68 are not obvious over the three cited references, and requests that the Examiner withdraw the rejection, or state it with greater clarity in her next action.

*The rejection over Seeman, Akintoye, Shibuya, and Lindmo*

The Examiner has rejected Claims 70 – 74 under 35 U.S.C. § 103(a) as allegedly being obvious over Seemann in view of Akintoye, and further in view of Shibuya, and further in view of Lindmo, U.S. Pat. No. 5,585,241 ("Lindmo").

Seemann and Akintoye do not disclose the use of two or more lectins for assessing a subject's susceptibility to caries. Neither Shibuya nor Lindmo discloses such a use. Instead, as discussed hereinabove, Shibuya only discloses a device that utilizes a very small amount of saliva (drop) for the diagnosis of dental caries. Lindmo only discloses a flow cytometry method

of detecting multiple analytes using different sized particles without showing any particular applicability to assessment of lectin binding.

Thus, Claims 70 – 74 are not obvious over the four cited references, and Applicant respectfully requests that the rejection be withdrawn.

### CONCLUSION

In view of the above remarks, Applicant respectfully submits that the subject application is in good and proper order for allowance. Withdrawal of the Examiner's rejections and early notification to this effect are earnestly solicited.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 839-5070.

No fee is believed owed in connection with filing of this amendment and reply. However, should the Commissioner determine otherwise, the Commissioner is authorized to charge any underpayment or credit any overpayment to Fish & Richardson P.C. Deposit Account No. 06-1050 (Ref. No. 19644-0005US1) for the appropriate amount.

Respectfully submitted,

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